IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

EVA S. SLOAN, Individually and as Executrix of The Estate of LOIS L. ESKIND, Deceased 1515 West Honeycut Road Kenefic, OK 74748	:	
Plaintiff	:	Civil Action No.
vs.	:	
SYNTHES, INC. 1302 Wrights Lane West Chester, PA 19380 And NORIAN CORPORATION 1302 Wrights Lane West Chester, PA 19380	:	
Defendants	:	

COMPLAINT

Plaintiff Eva S. Sloan, Individually and as Executrix of the Estate of Lois L. Eskind, Deceased, by and through her attorneys, Feldman & Pinto, herein presents her Complaint as follows:

Jurisdiction

1. Plaintiff, Eva S. Sloan, is an individual and a citizen of the State of Oklahoma, residing at 1515 West Honeycut Road, Kenefic, Oklahoma 74748, and she is the duly appointed Executrix, of the estate of Lois L. Eskind, who died on January 13, 2003.

2. Defendants Synthes, Inc. ("Synthes") and Norian Corporation ("Norian) are corporations organized under the laws of the State of Delaware with their principal place of business located at1302 Wrights Lane, West Chester, Pennsylvania, 19380.

3. The amount in the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

4. Jurisdiction of the United States District Court is based on the diversity of citizenship of the parties and the amount in controversy under 28 U.S.C.A. § 1332.

Venue

5. Venue is appropriate in the United States District Court for the Eastern District of Pennsylvania.

Factual Allegations

The Federal Food Drug & Cosmetic Act and the Federal Drug Administration

6. The Food and Drug Administration ("FDA") is an agency of the United States government, created by the federal Food, Drug, and Cosmetic Act ("FDC Act") (21 U.S.C.A. §§ 301-397) and is charged by the FDC Act with the responsibility of protecting the health and safety of the public by assuring, among other things, that medical devices intended for use in the treatment of humans are safe and effective for their intended uses and that the labeling of such devices bear true and accurate information. Pursuant to this statutory mandate, the FDA regulates the manufacturing, testing, labeling, and shipping of such devices in interstate commerce.

7. Under the FDC Act and the regulations promulgated pursuant thereto:

(a) An implant or other similar or related article which is intended for use in the treatment or prevention of disease of man or intended to affect the structure or any function of the body of man which does not achieve its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for

the achievement of its primary intended purposes is deemed to be a "device" (21 U.S.C.A. §§ 321(h).

(b) Each device falls into one of three regulatory categories, which are designated as Class I, Class II, and Class III. A Class III device is a device that presents a potential unreasonable risk of illness or injury and, therefore is subject to the most stringent regulatory requirements in order to provide reasonable assurance of its safety and effectiveness (21 U.S.C.A. §§ 351, 360c, 360e, 360j).

(c) A device is classified as a "significant risk device" if it presents a potential for serious risk to the health, safety or welfare of a human subject, or is a device that otherwise presents a potential for serious risk to the health, safety of welfare of a human subject (21 C.F.R. § 812.3(m)).

(d) Every manufacturer of a new Class III, significant risk device is required to obtain "Pre-Market Approval" from the FDA prior to marketing the device. In order to obtain this approval, a manufacturer must submit to the FDA an application for Pre-Market Approval and must provide the FDA with the results of clinical trials or investigations, involving the scientific testing of the device on human subjects to determine the safety and efficacy the device (21 U.S.C.A. §§ 360e, 355(d)).

(e) In seeking FDA approval to market a medical device, the manufacturer's application for approval must contain proposed labeling sufficient to describe the device, its intended use, and the directions for its use. The FDA's approval is then based on the stated intended use, and the FDA's approved use is required to be included in the device's labeling.

(f) In order to be able legally to perform the necessary clinical trials or investigations, a manufacturer of a Class III significant risk device is first required to obtain the FDA's approval for such trials and investigations by way of an Investigational Device Exemption and to obtain the approval of an investigational plan by an Institutional Review Board consisting of various experts, who will determine that the necessary requirements are met to minimize the risk to the subjects of the clinical trials (21 U.S.C.A. § 360e; 21 C.F.R. § 56.111(a)), and the unauthorized testing of a Class III significant risk device is illegal (21 U.S.C.A. § 351(f)(1)).

(g) Obtaining an Investigational Device Exemption to permit clinical trials and an Institutional Review Board to oversee the trials and planning and carrying out of the trials in order to obtain Pre-Market Approval by the FDA is an expensive and time consuming undertaking.

(h) A device that has received Pre-Market Approval must be marketed without significant deviations from the specification in the device's approval application since by approving a pre-market application, the FDA has determined that those specifications provide a reasonable assurance of safety and effectiveness. Therefore, in order for a manufacturer to be able legally to promote or market a previously approved device for a new use, the manufacturer must file with the FDA a supplemental application in order to obtain FDA approval for this new use (21 U.S.C.A. § 360e(d)(6); 21 C.F.R. § 814.39).

(i) The review process for approval of a new use for a previously approved device requires the manufacturer to provide the FDA with the results of clinical trials or investigations, involving the scientific testing of the device on human subjects. In order to be able legally to perform the necessary clinical trials or investigations, a manufacturer is

required first to obtain the FDA's approval for such trials and investigations by way of an Investigational Device Exemption and to obtain the approval of an investigational plan by an Institutional Review Board consisting of various experts, who will determine that the necessary requirements were met to minimize the risk to the subjects of the clinical trials (21 C.F.R. § 56.111(a)).

(j) An exception exists to the requirement of obtaining rigorous FDA approval of a Class III medical device if the device is "substantially equivalent" to a pre-existing device, known as a "predicate device," that already has FDA approval. In order to fall within this exception, a manufacturer must file a Pre-Market Notification with the FDA (21 U.S.C.A. §§ 360C(f), 360(k); 21 C.F.R. § 807.87). This notification is known as a "Special 510(k) Notification" referring to the section number of the predecessor to section 360(k) of the FDC Act. A special 510(k) notification must include, among other things, a statement of the intended use of the device, and if the intended use is different from the intended use of the previously approved use, the notification must include an explanation why the difference do not affect the safety or effectiveness of the device (C.F.R. §§ 807.87, 807.92). After receiving a special 510(k) notification, the FDA subjects the notification to a much less rigorous and much shorter process than is involved with an application for Pre-Market Approval. If the FDA finds that the device is, in fact, substantially equivalent to a previously approved device, the FDA gives the device a "clearance" (as opposed to an "approval"), and the device can be marketed without further regulatory analysis (21 U.S.C.A. §§ 360(o), 360e(b)(1); 21 C.F.R. § 100(b)). Clearance through the 510(k) process does not constitute FDA approval of the device, and any representation that creates an impression of official

approval of a device because of compliance with Pre-Market Notification regulations constitutes a misbranding of the device (21 C.F.R. § 807.97).

(k) Shipment of a medical device in interstate commerce must be accompanied by labeling bearing adequate directions for use for each of the device's intended uses.

(l) A Class III medical device is deemed "adulterated" if it does not have a required Pre-Market Approval or a required Investigational Device Exception (21 U.S.C.A. § 351(f)), and a medical device is deemed "misbranded" if the labeling does not bear adequate directions for use or if the manufacturer has failed to provide the FDA with Pre-Market Notification of a new or non-FDA-sanctioned intended use ninety days prior to introducing the device into interstate commerce for such use (21 U.S.C.A. § 352(f), (o); 21 C.F.R. § 807.81).

(m) The adulteration or misbranding of any device in interstate commerce or the introduction or delivery for introduction into interstate commerce of any adulterated or misbranded device is prohibited (21 U.S.C.A. § 331).

(n) A manufacturer is not permitted to promote a device for any use other than the intended use stated on the label as approved by the FDA.

(o) After a device has received Pre-Market Approval and is marketed, the manufacturer of a Class III medical device has a continuing duty to report to the FDA in a Medical Device Report information of which the manufacturer becomes aware from any source that reasonably suggests that the manufacturer's device might have caused or contributed to a death or serious injury (21 U.S.C.A. § 360i; 21 C.F.R. Parts 803, 820).

Vertebral Compression Fractures and Their Treatment

8. Each year, approximately 700,000 vertebral compression fractures due to osteoporosis, often in elderly people, occur in the United States, of which approximately 270,000 are painful and are clinically diagnosed.

9. In the early 1980s, a surgical procedure known as vertebroplasty was developed for treatment of vertebral compression fractures in which a needle is inserted into the fracture, and bone cement mixed with an x-ray contrast agent is injected in order to stabilize the fracture and alleviate back pain.

10. In the 1990s a variation of vertebroplasty was developed known as kyphoplasty in which a surgical instrument and a balloon are inserted into the fracture in order to expand the vertebra to its original shape before injecting bone cement mixed with an x-ray contrast agent.

The Defendants and Their Conduct

11. Prior to July 21, 1999, Synthes was in the business of developing, testing, manufacturing, labeling, promoting, distributing, and marketing various medical products. However, Synthes had no presence in the osteobilogic products market, which includes bone cement.

12. On July 21, 1999, Synthes acquired ownership of Norian, which was in the business of manufacturing, labeling, promoting, distributing, and marketing two identically formulated calcium phosphate bone cements under the names Norian Skeletal Repair System ("Norian SRS"), and Norian Cranial Repair System ("Norian CRS") in interstate commerce for use by the medical profession.

13. From July 21, 1999, and at all times thereafter relevant hereto, Norian was a wholly owned subsidiary of Synthes, and both Synthes and its subsidiary, Norian,

manufactured, labeled, promoted, distributed, and marketed Norian SRS and Norian CRS in interstate commerce.

14. Both Norian SRS and Norian CRS qualified as devices under the FDC Act and, therefore, their manufacture, labeling, promotion, testing, distribution, and marketing were subject to the provisions of the FDC Act and the regulations promulgated under the act.

15. Prior to the acquisition of Norian by Synthes on July 21, 1999, Norian had received Pre-Market Approval from the FDA to market Norian SRS for use in the distal radius (a long bone in the arm), and had received Pre-Market Approval from the FDA to market Norian CRS for filling defects in the skull.

16. In February 2000, the Chief Executive Officer of Synthes announced that the defendants would make "a strong push for vertebroplasty," and the defendants began exploring new markets for Norian SRS and for a new version of Norian SRS with radiopaque barium sulfate added, originally known as Norian SRS-R and eventually known as Norian XR (hereinafter referred to as "Norian XR"), for use in the treatment of vertebral compression fractures through vertebroplasty and kyphoplasty.

17. In early 2000, when Norian SRS was approved by the FDA only for use in the distal radius, the defendants devised a plan to conduct clinical trials of Norian SRS for use in treating vertebral compression fractures without FDA approval. This plan included identifying surgeons who would use Norian SRS in vetebroplasties and kyphoplasties, selecting test sites, providing Norian SRS to the surgeons, training the surgeons, observing the surgeries, and compiling and reviewing data.

18. In the spring of 2000, the defendants began planning to create a market for a Norian XR for use in vertebroplaties and kyphoplasties to treat vertebral compression fractures.

19. In the late summer of 2000, based on their exploration of the market by interviewing surgeons who were performing vertebroplasties and kyphoplasties, the defendants began developing a vertebroplasty system for the treatment of vertebral compression fractures. This system consisted of Norian XR and a group of instruments to be used for approaching the vertebral body to be treated and injecting the Norian XRS into the patient's back.

20. Norian SRS and Norian XR were each classified as Class III medical devices, and as significant risk devices and, therefore, approval of these devices for the new use of treating vertebral compression fractures required successful completion of the FDA's most stringent review process, including the filing of an application for Pre-Market Approval and providing the FDA with the results of clinical trials or investigations after obtaining an Investigational Device Exemption and the approval of an investigational plan by an Institutional Review Board.

21. Beginning at least as early as December 2000, the defendants received numerous warnings, including warnings from the FDA and from the defendants' own employees, that under the FDC Act and the regulations promulgated pursuant thereto, that in order to promote and market Norian SRS and Norian XR for treating vertebral compression fractures in procedures, such as vertebroplasty or kyphoplasty, it was necessary for the defendants to obtain FDA approval by way of a Pre-market Approval application; that in order to perform clinical tests of these devices on humans, it was necessary to obtain an Investigational

Device Exception from the FDA and the approval of an Investigational Review Board; that promoting these devices for such use without approval was illegal; and that training surgeons to use these devices for that purpose was illegal.

22. At least as early as October 2001, defendant's leaned that the FDA would not clear Norian SRS or Norian XR for such use by way of a 510(k) Pre-Market Notification, but would require Pre-Market Approval. Nevertheless, the defendants never sought and never obtained FDA approval for such use.

23. At least as early as March 2001, the defendants acquired actual subjective knowledge that Norian SRS and Norian XR, when injected into the spine for treatment of vertebral compression fractures, posed a serious and unreasonable lethal risk to patients, in that Norian SRS and Norian XR in their pre-hardened state when injected into the spine could leak into the venous system of the patient causing emboli and death. This knowledge included the following facts:

(a) In February 2001, two patients of a spine surgeon, Rick Delamarter, M.D., suffered severe non-fatal hypotensive episodes during kyphoplasty surgery to treat vertebral compression fractures using Norian CSR (the chemical equivalent of Norian SRS) . The first of these patients experienced a sever drop in blood pressure, after which it took about 20 minutes to stabilize the patient, and the patient spent three to four days in intensive care. The second patient experienced a severe drop in blood pressure but did not require admission to intensive care. A sales representative of the defendants had carried the Norian CSR to the operating room in each of these cases and was present in the operating room during each surgery..

(b) In April 2002, the University of Washington began pilot studies on Norian SRS and Norian XR commissioned by the defendants. On May 4, 2003, one of the researchers notified the defendants that upon injecting a relatively small dose of Norian XR into the spine of a pig, the entire pulmonary artery system clotted off and caused sudden death, underscoring the need for further investigation of the device while in its medication phase. The researcher also warned that there was a need to worry about a coagulogenic effect of the substance itself.

(c) On April 2, 2001, at a meeting convened by the defendants with certain surgeons to discuss the two hypotensive events, one prominent spine surgeon in attendance reported that Norian cement in its pre-hardened state might be interacting with blood and causing problems, and he believed it was critical to study the pre-hardened state of Norian cement before it was used in live patients because in its pre-hardened state, the cement had the potential to interact with tissues and blood in a way that hardened Norian cement did not.

(d) On or about June 28, 2002, the defendants received a letter from the University of Washington stating that the pilot studies showed that even a small amount of Norian SRS could generate the formation of large volumes of blood clot if the Norian SRS escaped from the bone into the venous circulation; that studies on human blood in test tubes showed that the calcium contained in the unique formulation of Norian SRS had a unique interaction with blood, providing both a surface on which clot formed and a chemical stimulus to clot formation; that the pilot studies further showed that following injection of a small amount of SRS, dramatic clotting of a pig's lung veins occurred, consistent with the human blood tests; and that the researchers believe that vertebroplasty presents a unique risk of Norian XR's

entry into the venous system with subsequent transport to the lung and a consequent risk of serious morbidity or mortality.

24. In or about November 2001, the defendants began training their spine sales force on the Norian XR and Cavity Creation System for performing vertebroplasties and kyphoplasties for the treatment of vertebral compression fractures.

25. In November 2001, at a management meeting attended by various of the defendants' top officials, the statutory procedure for obtaining FDA approval of the use of Norian SRS and Norian XR for treatment of vertebral compression fractures was described, and it was reported that following the legal statutory procedure would take 36 months at a cost of at least $1,000,000 and would result in the loss of whatever competitive edge the defendants had in the bone cement market.

26. After this meeting, because of the time and expense of following the legal statutory procedure for obtaining FDA approval, the defendants decided not to pursue the legal statutory procedure, and instead conspired with each other and with others to devise a fraudulent, tortious, and illegal scheme which the defendants subjectively knew to be in direct violation of the FDC Act and the regulations promulgated pursuant thereto and subjectively knew posed substantial and unreasonable risk of serious injury and death to patients.

27. The common purpose of this conspiracy was:

(a) to circumvent the application and clinical testing procedures mandated by the FDC Act and the regulations promulgated pursuant thereto, thus, avoiding the time and expense of complying with the Act and the regulations by creating an illegal "test market"

for the use of Norian SRS and/or Norian XR in the treatment of vertebral compression fractures without Pre-Market Approval or an Investigational Device Exception;

(b) to impede, impair, and defeat the lawful functions of the FDA to protect the health and safety of the public by ensuring that medical devices marketed and distributed in the United State were safe and effective for their intended uses, that the labeling of such devices bore true and accurate information, and that clinical investigation of significant risk devices was overseen by the FDA;

(c) to introduce into interstate commerce adulterated and misbranded medical devices, Norian SRS and Norian XR, for the intended use of treating vertebral compression fractures through vetebroplasty and kyphoplasty procedures, when Norian SRS and Norian XR had not received either Pre-Market Approval or Pre-Market Clearance for that intended use, and the defendants had actual subjective knowledge that this use of Norian SRS and Norian XR posed substantial and unreasonable risk of serious injury and death; and

(d) to establish an illegal test market project for the clinical testing on human beings of Norian SRS and Norian XR for treatment of vertebral compression fractures without an Investigational Device Exemption and the approval of an Institutional Review Board by obtaining a few sites where 60 to 80 such procedures could be performed, identifying surgeons who would participate in the illegal tests, by training these surgeons in the use of Norian SRS and/or Norian XR in the treatment of vertebral compression fractures, observing the surgeries, compiling and reviewing data from the surgeries, and having the surgeons publish the clinical results of their surgeries.

28. An integral part of the aforementioned scheme and conspiracy was the intentional, willful, and fraudulent concealment by the defendants' of their illegal activities

and the dangers inherent in those activities from the FDA, from the medical profession in general, from the defendants' own sales force, from the patients, from the patient's families, and from the public in general

29. This scheme and conspiracy included plans for the creation of an illegal test market for the use of Norian SRS and Norian XR in the treatment of vertebral compression fractures by identifying surgeons who would participate in the tests, selecting test sites, providing Norian SRS and/or Norian XR to the surgeons, training the surgeons in the use of Norian SRS and/or Norian XR in the treatment of vertebral compression fractures, observing the surgeries, compiling and reviewing data from the surgeries, having the surgeons publish the clinical results of their surgeries, and then marketing Norian SRS and Norian XR in interstate commerce for use in the treatment of vertebral compression fractures; all to without Pre-Market Approval or an Investigational Device Exception.

30. At all times relevant hereto, beginning at least as early as 20000, the defendants had actual knowledge that this scheme was illegal and in direct violation of the FDC Act and that this scheme and conspiracy posed a substantial and unreasonable risk of serious harm and death to the patients who would be injected with Norian SRS and/or Norian XR in the treatment of vertebral compression fractures, and both defendants knowingly, willfully, and intentionally ignored the risk and violated the FDC Act.

31. At some time prior to January 2003, the defendants in furtherance of the aforementioned scheme and conspiracy, enlisted a spine surgeon, Barton Sachs, M.D. ("Dr. Sachs"), as a co-conspirator, and from that time on, Dr. Sachs became a co-conspirator of the defendants with the same unlawful common purpose as the defendants, and as set forth

below, Dr. Sachs committed numerous overt acts in furtherance of the unlawful conspiracy, of which he was a part.

32. In furtherance of the aforementioned scheme and conspiracy, beginning no later than November 2001, the defendants, acting jointly and in concert, through their officers, directors, and employees within the scope of their employment, knowingly, willfully and intentionally embarked on the following continuous course of fraudulent, tortious, and illegal overt acts and conduct, including the failure to perform acts that they were under a legal duty to perform:

(a) The defendants knowingly, willfully, and intentionally promoted the off-label use of Norian SRS and Norian XR, both of which were adulterated and misbranded devices, for treatment of vertebral compression fractures without FDA approval while concealing from the medical profession in general, from the defendants' own sales force, and from the patients, and the patients' families, and from the public in general the fact that Norian SRS and Norian XR were not legally intended for the treatment of vertebral compression fractures and that a small amount of Norian SRS or Norian XR if injected into the spine could leak into the venous system of the patient, where it could cause blood clot formation, leading to serious injury and death.

(b) Despite the fact that neither Norian SRS nor Norian XR was approved by the FDA for the treatment of vertebral compression fractures, the defendants, beginning in 2001, and at various times thereafter, the defendants knowingly, willfully, and intentionally approved, organized, sponsored, and their employees attended forums at which, as a means of creating an illegal test market, they trained approximately fifty carefully selected spine surgeons how to mix Norian SRS with barium sulfate and how to use the mixture to treat

vertebral compression fractures. The defendants' sales force would then gather clinical data about the surgeries that the "test market" surgeons performed in order to create a body of information about the risk level of using Norian SRS and Norian XR for the treatment of vertebral compression fractures.

(c) The defendants directed their employees to attend vertebroplasties and kyphoplasties in which Norian SRS mixed with barium sulfate or Norian XR was used to treat vertebral compression fractures and to gather safety and efficacy information from surgeons who were using Norian SRS mixed with barium sulfate or Norian XR was used to treat vertebral compression fractures.

(d) In December 2001, the defendants, by means of a 510(k) notification, obtained FDA approval to market Norian SRS as a general bone void filler subject to the restriction that it could be used to fill only those bony voids that were not intrinsic to the stability of the bony structure in the extremities, spine, or pelvis, and that it was not to be mixed with any other substance. In applying for this approval, the defendants fraudulently and illegally failed to inform the FDA of their true intention to promote and market Norian SRS to be mixed with barium sulfate in the operating room for use in vertebroplasties and kyphoplasties for the treatment of vertebral compression fractures.

(e) In a May 8, 2002 telephone conference with the FDA, in response to the FDA's request that the labeling of the defendants' bone cements clearly specify that the cements were not to be used in treatment of spinal compression fractures in such procedures as vertebroplasty and kyphoplasty, the defendants fraudulently promised and misrepresented that they would not promote Norian XR for such indications or other load bearing applications without the appropriate regulatory clearance, which the defendants knew to be

Pre-Market Approval and an Investigational Device Exemption. However, at the time of this telephone conference, the defendants' true intention was to test, promote and market Norian SRS and Norian XR for use in treatment of spinal compression fractures in such procedures as vertebroplasty and kyphoplasty was to the contrary, and the defendants had already taken steps to implement their aforementioned scheme and conspiracy to accomplish that purpose.

(f) At the end of May 2002, despite their knowledge of the serious and unreasonable risks to patients when Norian SRS is injected into the spine, despite their May 8, 2002 promise to the FDA, despite the advise of the FDA and the defendants' own employees, despite the restrictions on the Norian SRS label, which stated that it was not to be mixed with any other substance, and despite their knowledge of the illegality of their promoting an off-label use of Norian-SRS, the defendant approved the test market for SRS in treating vertebral compression fractures.

(g) In August 2002, the defendants began the illegal test market, training spine surgeons to mix Norian SRS with barium sulfate and to use the resulting mixture in vertebroplasty-type surgeries to treat vertebral compression fractures. This mixture of Norian SRS with barium sulfate created a new device and its use in vertebroplasty-type surgeries to treat vertebral compression fractures constituted a new use, both of which required Pre-Market Approval by the FDA.

(h) In September 2002, in direct violation of the Norian SRS label, which stated that it was not to be used in bones intrinsic to the stability of the bony structure and was not to be mixed with any other substance, and in direct violation of their promise to the FDA, the defendants knowingly, willfully, and intentionally began a process of having its employees mix barium sulfate with Norian SRS in the operating room for use by surgeons performing

vertebroplasties and kyphoplasties. This process, which was known as "back table mixing," enabled the defendant ostensibly to promote the use of Norian SRS rather than Norian XR, which, unlike Norian SRS, had an explicit prohibition in its labeling that it was "not intended for the treatment of vertebral compression fractures." Of course, once the mixing occurred, the mixture was identical to Norian XR.

(i) On or about November 18, 2002, the defendants submitted to the FDA a special 510(k) notification for Norian XR requesting clearance for a general bone void filler indication, listing Norian as the manufacturer and stating that Norian XR was substantially equivalent to Norian SRS. Despite their promise to the FDA during the May 8 2002 telephone conference, the defendants knowingly, willfully, and intentionally omitted from the notification the language requested by the FDA stating that Norian XR was not intended for load bearing indications such as treating vertebral compression fractures. Furthermore, the defendants fraudulently and illegally failed to inform the FDA that their true intention was to market Norian XR for use in vertebroplasties and kyphoplasties for the treatment of vertebral compression fractures, or that they had already engaged in mixing Norian SRS with barium sulfate, creating the chemical equivalent of Norian XXR, and promoting and marketing the mixture for use in vertebroplasties and kyphoplasties for the treatment of vertebral compression fractures.

(j) On December 19, 2002, in response to defendants' Special 510(k) Notification, the FDA cleared Norian XR as a general bone void filler, with identical restrictions on the indication for its use as that for Norian SRS, i.e., that it could be used to fill only those bony voids not intrinsic to the stability of the bony structure in the extremities, spine, or pelvis,

but also with an additional explicit warning, added at the insistence of the FDA, that Norian XR was "[n]ot intended for the treatment of vertebral compression fractures."

(k) On January 13, 2003, less than a month after the defendants received special 510(k) clearance from the FDA to market Norian XR subject to the foregoing restrictions, a spine surgeon, Dr. Sachs, mixed Norian SRS with barium sulfate, thus, creating a device identical to Norian XR, and in order to treat a vertebral compression fracture performed a vertebroplasty/kyphoplasty on plaintiff's decedent, using defendant's cavity creation instruments and injecting the mixture into her spine, causing her death, as more fully set forth below. One of defendants' sales consultants was present in the operating room throughout the surgery, including when the Norian SRS was mixed with barium sulfate, the mixture was injected, and when the death occurred.

(l) Despite the fact that the defendants, became aware from its own employee who was present in the operating room and from other sources, that their device, Norian SRS mixed with barium sulfate, might have caused or contributed to the death of the plaintiff's decedent, the defendants with the intention of concealing the death from the FDA, the medical profession in general, the family of the plaintiff's decedent, and the public in general, knowingly, willfully, and intentionally failed and refused to file a Medical Device Report concerning the death of the plaintiff's decedent as they were required to do by the FDC Act and the regulations promulgated pursuant thereto.

(m) Despite a warning by one of their own employees, on January 28, 2003, that a communication must be sent to defendants' sales force warning them not to promote Norian SRS or Norian XR for off-label uses, in particular for treatment of vertebral compression

fractures, the defendants knowingly, willfully, and intentionally failed and refused to send any such communication to their sales force.

(n) On or about February 10, 2003, after consultation with Dr. Sachs about the death of the plaintiff's decedent, the defendants approved the Final Market Introduction Plan for Norian XR, which was predicted to bring in a more than $3 million in first-year after-tax profits.

(o) On February 26, 2003, in response to an inquiry by the defendants as to whether Norian XR could be used to treat vertebral compression fractures as long as it was used with supplemental fixation, the FDA responded by stating that the use of Norian XR to treat vertebral compression fractures had not been cleared, and that such use would constitute a new use, requiring Pre-Market Approval based on clinical data.

(p) On July 18, 2003, a Safety Meeting was held by a group of the defendants' senior officers and employees for the explicit purpose of considering whether Norian XR was safe enough to bring to market and whether to abandon the illegal test market project or to place the defendants' business interests over the safety of patients. At the meeting, the fact was discussed that there had been three adverse events (two severe hypotensive events and one death) out of 34 vertebral compression fracture cases to date, a statistically significant percentage. One participant pointed out that "There's a massive cover-up" and "many clinical problems." Nevertheless, the defendants knowingly, willfully, and intentionally decided that despite the serious risks to the patients and the illegality of their conduct, they would proceed aggressively with the unauthorized and illegal clinical testing of Norian SRS and Norian XR on human beings.

(q) On August 14, 2003, a Strategic Planning Meeting was held by certain of the defendants executives and certain surgeons. At this meeting, the defendants' executives directed that the illegal Norian XR test market continue despite a recommendation by one of the surgeons that an FDA study be conducted of Norian XR to gain approval for its use in vetebroplasties.

(r) On August 15 and 16, 2003, in San Diego, California, the defendants held the first surgeon training meeting of the illegal Norian XR test market. The meeting included defendants' sales representatives and spine surgeons who were selected by the defendants based on their experience in performing vertebroplasties, and whose expenses were paid by the defendants. Lectures and PowerPoint presentations were given to the attendees concerning the use of Norian XR in vertebroplasties to treat vertebral compression fractures, and in a cadaver laboratory, the surgeons were taught how to inject Norian XR into the vertebral bodies of cadavers. The defendants did not inform the surgeons of the death of the plaintiff's decedent, of the other adverse results during surgery, or of the laboratory findings at the University of Washington concerning blood clots. Notebooks were distributed to the attending spine surgeons and sales representatives containing forms designated as "Test Market Reorder Forms" to be used in reordering Norian XR. The notebook also contained instructions that Norian XR could not be reordered unless the surgeon filled out a Test Market Recorder Form with information about each surgery performed with Norian XR.

(s) In August 2003, the defendants released Norian XR to the test market, shipping the product to 17 sites for use in vertebroplasty/kyphoplasty surgery for treatment of vertebral compression fractures.

(t) On September 19, 2003, a spine surgeon, Paul Nottingham, M.D, used defendants cavity creation instruments and Norian XR in order to treat a vertebral compression fracture in a patient, who died on the operating table after suffering a hypotensive episode shortly after the injection of the Norian XR. Dr. Nottingham noted a cement leak and believed that it was the cause of the episode and could not rule out Norian XR as the cause of death. One of defendants' sales consultants was present in the operating room throughout the surgery, including when the Norian XR was injected, and when the death occurred. Dr. Nottingham complained that the defendants' sales representative had "pushed" Norian XR on him and that the sales representative was unclear as to its status on the market

(u) Despite the fact that the defendants became aware from its own employee who was present in the operating room and from other sources, that their device, Norian XR might have caused or contributed to the death of Dr. Nottingham's patient, the defendants with the intention of concealing the cause of the death from the FDA, the medical profession, and the public, knowingly, willfully, and intentionally filed a Medical Device Report that was brief, vague, inadequate, and misleading, and did not mention that the procedure was a vertebroplasty/kyphoplasty using Norian XR or that it involved a vertebral compression fracture.

(v) On September 19 and 20, 2003, at Charlotte, North Carolina, the defendants held the second Norian XR test market training session for surgeons. The format of this session was identical to that of the session held in San Diego in August 2003. The attendees were spine surgeons selected by the defendants based on their experience in performing vertebroplasty surgery. Again the surgeons' expenses were paid by the defendants. At this session, the defendants, with the fraudulent intent to conceal the adverse effects of using

Norian SRS or Norian XR in vertebroplasty/kyphoplasty surgery did not inform the trainee surgeons of the first two deaths, of other adverse effects on human patients, or of adverse effects during animal studies performed at the University of Washington.

(w) On October 24, 2003, various employees of the defendants held a meeting with various spine surgeons to plan upcoming Norian XR surgeon training forums. At the meeting it was agreed that the defendants would "target spine surgeons as the primary attendees;" that the defendants' spine sales consultants would attend the forums with their surgeons; and that the forums would include both lectures and cadaver laboratories.

(x) At a meeting held on October 31, 2003, the defendants considered serious questions concerning the use of Norian XR in the unauthorized clinical trials. Despite the second death and escalating knowledge of the substantial serious risks in the use of Norian XR in vertebral compression fracture surgery, the defendants decided to continue the experimental use of Norian XR on humans.

(y) On November 23 and 24, 2003, the defendants held a meeting of its spine sales force, at which a spine surgeon who had been invited by the defendants gave a lecture to the defendants' spine sales force concerning the use of Norian XR in vertebroplasties to treat vertebral compression fractures.

(z) In December 2003, the defendants released a Norian XR Technique Guide to their spine sales force together with CD-Rom that included depictions of the off-label use of Norian XR in the treatment of vertebral compression fractures, including x-rays of the spine of plaintiff's decedent with depiction of the injected SRS. However, defendants knowingly, willfully, and intentionally omitted from said guide and CD-ROM any disclosure or

statement of the specific warning on the Norian XR label that it was not intended for treatment of vertebral compression fractures.

(aa) On December 31, 2003, the defendants released Norian XR for sale beyond the initial test market.

(bb) On January 10 and 11, 2004, the defendants held a forum at which approximately 30 spine surgeons were trained to use Norian XR to treat vertebral compression fractures. Dr. Sachs participated in conducting the forum, and the defendants delegated to Dr. Sachs the task of explaining to the attendees the warning on the Norian XR label that Norian XR was "not intended for treatment of vertebral compression fractures." Dr. Sachs reworded the warning in such a way as to obfuscate its meaning, and the defendants employees did nothing to dispel the confusion created by Dr. Sachs.

(cc) On January 22, 2004, a spine surgeon, Hieu Ball, M.D, used Norian XR in kyphoplasty surgery in order to treat a vertebral compression fracture in a patient, who died on the operating table after suffering a hypotensive episode shortly after the injection of the Norian XR.

(dd) Despite the fact that the defendants became aware that their device, Norian XR might have caused or contributed to the death of Dr. Nottingham's patient, the defendants with the intention of concealing the cause of the death from the FDA, the medical profession, and the public, knowingly, willfully, and intentionally filed a Medical Device Report that was brief, vague, inadequate, and misleading, and did not mention that the procedure was a kyphoplasty using Norian XR or that it involved a vertebral compression fracture. After receiving a copy of the autopsy report, which showed that foreign material

was found in the L-2 vertebral body and in microscopic vessels of the lungs, the defendants knowingly, willfully, and intentionally failed to supplement the Medical Device Report.

(ee) On February 10, 2004, defendants sent a "Dear Surgeon" letter to all surgeons who had been selected by the defendants to operate in the unauthorized clinical trials. The letter was intentionally misleading and was primarily designed to protect the business interests of the defendants and their officers rather that the safety of members of the public, in that the letter did not contain a clear statement of the dangers posed by the use of Norian SRS and Norian XR in the treatment of vertebral compression fractures, of which the defendants had longtime knowledge, did not state anything about the three deaths or the two hypotensive events that occurred using Norian bone cements, and said nothing about the clear warnings the defendants had received from researchers at the University of Washington about the lethal risks of leakage and blood clotting when using Norian bone cements in animals.

(ff) On February 12, 2004, after the third death, the defendants knowingly, willfully, and intentionally failed and refused to recall and remove Norian XR from the market, and failed and refused to notify the FDA that this device might pose a significant risk to human safety, but instead removed the restriction on the inventory of Norian XR, releasing it for sale beyond the original test market, so that it could be purchased by any surgeon or hospital. The defendants then informed their spine sales force that Norian XR was not the subject of a recall and was not being pulled from the market, leading to the performance of several additional off-label surgeries to treat vertebral compression fractures with Norian XR.

(gg) From May 11 to June 18, 2004, an inspector for the FDA conducted an on-site inspection of Norian at 1230 Wilson Drive, West Chester, Pennsylvania. During the inspection, the defendants' officers and employees knowingly, willfully, and intentionally made false, fraudulent, and misleading statements to the FDA inspector, including the following: that neither Synthes nor Norian had marketed or promoted Norian SRS or Norian XR for the treatment of vertebral compression fractures; that neither Synthes nor Norian had tested Norian SRS or Norian XR on human subjects for the treatment of vertebral compression fractures; that neither Synthes nor Norian had a vertebroplasty system; that many uses of Norian XR in association with vertebroplasty and kyphoplasty are completely appropriate and on label; that the Norian test market discussed at the July 18, 2003, Safety Meeting involved approved indications for Norian XR; that surgeons were mixing SRS with barium sulfate "on their own;" and that the 34 test market cases discussed at the July 18, 2003 Safety Meeting involved only data that the defendants had collected about what surgeons were doing on their own, rather than a test market conducted by the defendants. The defendants' purpose in making these false, fraudulent and misleading statements was to lull the FDA, to impair and impede its lawful functions, including its function of overseeing device manufacturers, and to avoid FDA scrutiny into the three deaths that had occurred during the illegal test market.

(hh) During July 2004, in order to impede the FDA from carrying out its lawful functions, including scrutinizing the three deaths that occurred during the test market, the defendants knowingly, willfully, and intentionally made a series of false statements to the FDA in response to the FDA's observations concerning the aforementioned inspection by the FDA conducted in May and June 2004, including the following: that the Norian XR test

market was for cleared indications instead of the treatment of vertebral compression fractures; that the test market was not designed to obtain safety and efficacy information from surgeons about the use of Norian XR to treat vertebral compression fractures; that the two test market surgeon training meetings and the surgeon forum had not trained surgeons how to use Norian XR to treat vertebral compression fractures; that at the time of the test market activities, the defendants did not intend to market Norian XR for the treatment of vertebral compression fractures; that it was never the defendants' intent to suggest, in any way, that Norian XR should be used for the purpose of treating vertebral compression fractures; and that the defendants did not promote Norian XR for the off-label use of treating vertebral compression fractures.

(ii) After receiving a warning letter from the FDA dated November 5, 2004, the defendants sent a written response to the FDA knowingly, willfully, and intentionally making false, fraudulent, and deceptive statements that no clinical trials of Norian SRS or Norian XR had occurred, that the test market of Norian SRS and Norian XR had been conducted only for cleared indications, that the test market of Norian SRS and Norian XR was not conducted for the purpose of testing the safety and efficacy of Norian SRS or Norian XR, and that the defendants had not trained surgeons to use Norian SRS or Norian XR.

Conduct in Support of the Conspiracy of Barton Sachs, M.D.

33. In furtherance of the aforementioned scheme and conspiracy, Barton Sachs, M.D. knowingly, willfully and intentionally embarked on a continuous course of fraudulent, illegal, and tortious conduct including committing the following overt acts and failing to perform the following acts that as a physician, he was under a legal duty to perform:

(a) Dr. Sachs participated in the defendants' illegal test market project for the clinical testing of Norian SRS and Norian XR, performing several surgeries to treat vertebral compression fractures, using either Norian SRS back table mixed with barium sulfate or Norian XR, including the surgery he performed on the plaintiff's decedent on January 13, 2003.

(b) Dr. Sachs advised his patients, who were suffering from symptomatic vertebral compression fractures to undergo vertoplasty/kyphoplasty surgery with Norian SRS or Norian XR, while he intentionally, knowingly, and fraudulently failed to inform the patients of the following facts, which he subjectively knew, which would influence a reasonable person in making a decision to give or withhold consent to surgery, and of which he as a physician had a legal duty to inform his patients:

(i) The surgery involved the use of an illegally promoted medical device that was not approved by the FDA for that use, and that the FDA had explicitly warned should not be so used;

(ii) The medical device that was to be used in the surgery posed a unique serious and unreasonable risk of severe harm and death.

(iii) The surgery was experimental and was part of an illegal clinical test of the medical device, and that the patients were being used as a human guinea pigs.

(iv) Dr. Sachs had a financial interest in the use of Norian SRS and Norian XR in treating vertebral compression fractures and, therefore, had a conflict of interest in recommending surgery using Norian SRS and Norian XR.

(v) There were other less risky methods of treatment,.

(c) Despite Dr. Sachs' duty as plaintiff's decedent's physician to inform her of the nature and inherent risks the surgery that he proposed to perform on her on January 13, 2003, he intentionally and fraudulently failed to inform the plaintiff's decedent of the foregoing facts, of which he had actual subjective knowledge, but instead merely told the plaintiff's decedent that he had had good success with the product he was going to inject into her spine:

(d) After the plaintiff's decedent's death, although Dr. Sachs believed that the Norian SRS mixed with barium sulfate that he had injected into plaintiff's decedent's spine might have been the cause of her death, in order to conceal any possible connection between the defendants' device and her death, he failed to inform the plaintiff or any other member of the plaintiff's decedent's family of that fact, but instead merely stated without explanation, "She didn't make it. I'm sorry."

(e) In order to further conceal the connection between the defendant's product to the plaintiff's decedent's death, Dr. Sachs filled out the death certificate, without an autopsy, stating that the immediate cause of her death was "acute myocardial infarction" and the underlying cause was "chronic myocardial ischemic disease" and prior myocardial infarctions" without any mention that Norian SRS may have been the cause of the plaintiff's decedent's death.

34. In January or February 2003, Dr. Sachs consulted with several of the defendants' high ranking employees about the death of the plaintiff's decedent as a prelude to the defendants approval of their the Final Market Introduction Plan for Norian XR.

35. Dr. Sachs attended the October 24, 2003, meeting with various employees of the defendants to plan upcoming Norian XR surgeon training forums. At the meeting it was

agreed that the defendants would "target spine surgeons as the primary attendees;" that the defendants' spine sales consultants would attend the forums with their surgeons; and that Dr. Sachs would serve as a faculty chairman for the surgeon forums, which would include both lectures and cadaver laboratories.

36. At the request of the defendants and without the permission of plaintiff's decedent or her family, Dr. Sachs released to the defendants x-rays of plaintiff's decedent's spine taken during the surgery of January 13, 2003. The defendants then, in December 2003, included the x-rays in the Technique Guide referred to above, that was distributed to their spine sales force together with CD-Rom that included depictions of the off-label use of Norian XR in the treatment of vertebral compression fractures without any indication that the plaintiff's decedent had died during the surgery and without any indication of adverse effects from other such surgeries.

37. Dr. Sachs participated in conducting the forum the January 10 and 11, 2004 forum held by the defendants at which approximately 30 spine surgeons were trained to use Norian XR to treat vertebral compression fractures, and the defendants delegated to Dr. Sachs the task of explaining to the attendees the warning on the Norian XR label that Norian XR was "not intended for treatment of vertebral compression fractures." Dr. Sachs intentionally reworded the warning in such a way as to obfuscate its meaning, and the defendants employees did nothing to dispel the confusion created by Dr. Sachs.

Causation

38. The aforementioned illegal scheme and conspiracy, the fraudulent, illegal, and tortious conduct of the defendants and their co-conspirator, Dr. Sachs was a direct, proximate, and producing cause of the plaintiff's decedent's uninformed consent to undergo

the surgery performed on her by Dr. Sachs on January 13, 2003, at the Texas Back Institute in Plano, Texas, during which Dr. Sachs injected into the plaintiff's decedent's spine Norian SRS, which had been back table mixed with barium sulfate, and which leaked into the plaintiff's decedent's venous system causing emboli, which traveled to her lungs, causing a severe hypotensive event and causing her death on the operating table shortly after the injection.

COUNT I – SURVIVAL ACTION
Fraud and Conspiracy to Commit Fraud
Plaintiff Eva S. Sloan, Executrix of the Estate of Lois L. Eskind, Deceased v. Defendants

39. Plaintiff incorporates the preceding paragraphs 1 through 38 inclusive, as if fully set forth herein at length.

40. Plaintiff as Executrix of the Estate of Lois L. Eskind, Deceased, brings this action pursuant to the Pennsylvania Probate, Estate and Fiduciary Code, 20 Pa.C.S. section 3371 and 3373, and 42 Pa.C.S. Section 8302.

41. Plaintiff's decedent would have been entitled to bring an action for the injury if she had lived.

42. As a direct and proximate result of the negligence and carelessness of Defendants, and/or their agents, servants, workers, or employees and/or others for whose acts or omissions it is responsible and whose identities are in the exclusive control of Defendants, Lois L. Eskind suffered the following damages:

(a) Plaintiff's decedent suffered physical injuries to her body including, but not limited to, aches, pains, mental anxiety, anguish and the severe shock through her nerves

and nervous system, together with internal injuries of an unknown nature and other injuries the full extent of which resulted in the death of Lois L. Eskind;

(b) Plaintiff's decedent underwent extensive surgical, hospital, medical and nursing care, all to her great financial detriment;

(c) Plaintiff's decedent was unable to attend to her usual duties, occupation or avocations and was disabled in the past from performing her usual duties, occupations and avocations with consequent additional financial detriment;

(d) Plaintiff's decedent underwent grievous bodily pain and suffering, disfigurement, mental anguish, inconvenience, embarrassment, humiliation and loss of enjoyment of life.

43. The foregoing false and fraudulent statements and representations made by the defendants and by Dr. Sachs were material to the surgery performed on plaintiff's decedent by Dr. Sachs on January 13, 2003, which caused the death of the plaintiff's decedent in that they concealed the illegality, experimental nature, and the substantial risks of the surgery.

44. When the defendants and Dr. Sachs made each of the foregoing false and fraudulent statements and representations, the defendants and Dr. Sachs knew that each statement and representation was false, or in the alternative, the defendants and Dr. Sachs made each of the foregoing false and fraudulent statements and representations recklessly as a positive assertion knowing that they lacked any knowledge of the truth.

45. The defendants and Dr. Sachs made each of the foregoing false and fraudulent statements and representations with the intent that the FDA, the defendants' own sales force, the spine surgeons in general, and the patients, including the plaintiff's decedent, should act upon them.

46. In addition to the defendants' and Dr. Sachs' foregoing false and fraudulent statements and representations, the defendants and Dr. Sachs, as alleged above, fraudulently and with the intent to deceive failed to disclose to the FDA, to their own sales force, to the spine surgeons in general, and to the patients, undergoing surgery with Norian SRS and Norian XR, including plaintiff's decedent, facts that they were under a duty to disclose under the FDC Act and under the circumstances.

47. The foregoing facts that the defendants and Dr. Sachs fraudulently failed to disclose were material to the surgery performed on plaintiff's decedent by Dr. Sachs on January 13, 2003, which caused the death of the plaintiff's decedent in that the failure to disclose said facts concealed the illegality, the experimental nature, and the substantial risks of the surgery.

48. The foregoing facts that the defendants and Dr. Sachs failed to disclose were facts within the defendants' and Dr. Sachs' actual subjective knowledge.

49. At all times relevant hereto, the defendants and Dr. Sachs had actual subjective knowledge that the FDA, the defendants' sales force, surgeons in general who were using Norian SRS and Norian XR, and the patients undergoing surgery with Norian SRS and Norian XR, including plaintiff's decedent, neither knew nor in the exercise of reasonable care should have known of the facts the defendants and Dr. Sachs failed to disclose and did not have an equal opportunity to discover the truth.

50. In making the foregoing false and fraudulent material statements and representations, and in failing to disclose the foregoing material facts, the defendants and Dr. Sachs intended:

(a) to impede the FDA from performing its lawful functions to protect the health and safety of the public, including plaintiff's decedent, by ensuring that Norian SRS and Norian XR were safe and effective for their intended use, and from enforcing the FDC Act by preventing the illegal and unreasonably dangerous use of Norian SRS and Norian XR in surgery to treat vertebral compression fractures;

(b) to induce the defendants' sales force to promote the use of Norian SRS and Norian XR in surgery to treat vertebral compression fractures to spine surgeons, including Dr. Sachs;

(c) to induce spine surgeons, to use Norian SRS and Norian XR in surgery to treat vertebral compression fractures and to prevent spine surgeons from warning their patients, including plaintiff's decedent, of the illegality and substantial risks of the surgery;

(d) to induce patients, including the plaintiff's decedent, to assent to surgery using Norian SRS or Norian XR to treat vertebral compression fractures.

51. At all times relevant hereto, the FDA, the defendants' own sales force, the spine surgeons, and the patients, including the plaintiff's decedent, justifiably relied on the defendants' and Dr. Sachs' fraudulent statements and representations and on the absence of the facts that the defendants and Dr. Sachs fraudulently failed to disclose.

52. The foregoing false and fraudulent statements and representations of the defendants and Dr. Sachs, and the foregoing failure of the defendants and Dr. Sachs to disclose material facts were the direct, proximate, and producing cause of:

(a) the impeding of the FDA from performing its lawful functions to protect the health and safety of the public, including plaintiff's decedent, by ensuring that Norian SRS and Norian XR were safe and effective for their intended use, and from enforcing the FDC

Act by preventing the illegal and unreasonably dangerous use of Norian SRS and Norian XR in surgery to treat vertebral compression fractures;

(b) the vigorous promotion by the defendants' sales force of Norian SRS and Norian XR to physicians for use in vertebroplasties and kyphoplasties in treating vertebral compression fractures;

(c) the failure of Dr. Sachs' to warn the plaintiff's decedent of the serious and unreasonable risks of the surgery she agreed to undergo on January 13, 2003, and Dr. Sachs' performing said surgery on plaintiff's decedent on January 13, 2003, without the patient's informed consent;

(d) the plaintiff's decedent's uninformed consent to the aforementioned surgery, and the plaintiff's decedent's undergoing said surgery;

(e) the plaintiff's decedent's death during surgery;

(f) the injury and damages suffered by the plaintiff's decedent's husband and children as more fully set forth below.

53. As set forth above, the defendants combined together with each other and with Dr. Sachs in order to accomplish the aforementioned unlawful common purposes.

54. At all times relevant hereto, the defendants and Dr. Sachs had a meeting of the minds on the object of their conspiracy and on the course of action to accomplish their common purposes.

55. As set forth above, the defendants and Dr. Sachs committed numerous overt acts in furtherance of their common purposes including actively concealing their illegal activities and the dangers inherent in those activities from the FDA, the medical profession in general, the defendants' own sales force, the patients, the patient's families, and the public in general.

56. As co-conspirators each of the defendants is vicariously liable for all acts done by any of their co-conspirators in furtherance of the conspiracy, including all acts done by Dr. Sachs in furtherance of the conspiracy.

57. The conspiracy and the acts and omissions of the defendants' and Dr. Sachs' committed in furtherance of their conspiracy were a direct, proximate, and producing cause of :

(a) the impeding of the FDA from performing its lawful functions to protect the health and safety of the public, including plaintiff's decedent, by ensuring that Norian SRS and Norian XR were safe and effective for their intended use, and from enforcing the FDC Act by preventing the illegal and unreasonably dangerous use of Norian SRS and Norian XR in surgery to treat vertebral compression fractures;

(b) the vigorous promotion by the defendants' sales force of Norian SRS and Norian XR to physicians for use in vertebroplasties and kyphoplasties in treating vertebral compression fractures;

(c) the failure of Dr. Sachs' to warn the plaintiff's decedent of the serious and unreasonable risks of the surgery she agreed to undergo on January 13, 2003, and Dr. Sachs' performing said surgery on plaintiff's decedent on January 13, 2003, without the patient's informed consent;

(d) the plaintiff's decedent's uninformed consent to the aforementioned surgery, and the plaintiff's decedent's undergoing said surgery;

(e) the plaintiff's decedent's death during surgery;

(f) the injury and damages suffered by the plaintiff's decedent's husband and children as more fully set forth below.

WHEREFORE, Plaintiff claims damages in an amount in excess of $75,000.00 exclusive of interest and costs, and demands judgment in her favor and against all other parties.

COUNT II – SURVIVAL ACTION
Willful, Wanton, Malicious and Reckless Misconduct
Plaintiff Eva S. Sloan, Executrix of the Estate of Lois L. Eskind, Deceased v. Defendants

58. Plaintiff incorporates the preceding paragraphs 1 through 57 inclusive, as if fully set forth herein at length.

59. The foregoing acts and omissions of the defendants were intentional and constituted willful, wanton, malicious, and reckless misconduct that was outrageous because of the defendants' evil motive, the defendants' actual subjective appreciation of the risk, and the defendants acting and failing to act in conscious disregard of that risk,

60. At all times relevant hereto, the defendants have actual subjective knowledge that their aforementioned conduct created a substantial and unreasonable risk of physical harm and death to the patients who were injected with Norian SRS or Norian XR during surgery for treatment of vertebral spinal fractures, including the plaintiff's decedent, but, nevertheless, intentionally acted and failed to act in conscious and deliberate disregard of the risk..

61. The defendants' willful, wanton, malicious, and reckless misconduct was a direct, proximate, and producing cause of the death of the plaintiff's decedent and the injury and damage to the plaintiff's decedent's estate and to the plaintiff's decedent's husband and children as more fully set forth below.

62. The vast bulk of the foregoing acts and omissions of the defendants and all of the decision making of the defendants with regard to the foregoing acts and omissions occurred in the Commonwealth of Pennsylvania, where the defendants' principal places of business were located.

63. The foregoing willful, wanton, malicious, and reckless misconduct of the defendants was the direct, proximate, and producing cause of:

(a) the impeding of the FDA from performing its lawful functions to protect the health and safety of the public, including plaintiff's decedent, by ensuring that Norian SRS and Norian XR were safe and effective for their intended use, and from enforcing the FDC Act by preventing the illegal and unreasonably dangerous use of Norian SRS and Norian XR in surgery to treat vertebral compression fractures;

(b) the vigorous promotion by the defendants' sales force of Norian SRS and Norian XR to physicians for use in vertebroplasties and kyphoplasties in treating vertebral compression fractures;

(c) the failure of Dr. Sachs' to warn the plaintiff's decedent of the serious and unreasonable risks of the surgery she agreed to undergo on January 13, 2003, and Dr. Sachs' performing said surgery on plaintiff's decedent on January 13, 2003, without the patient's informed consent;

(d) the plaintiff's decedent's uninformed consent to the aforementioned surgery, and the plaintiff's decedent's undergoing said surgery;

(e) the plaintiff's decedent's death during surgery;

(f) the injury and damages suffered by the plaintiff's decedent's husband and children as more fully set forth below.

WHEREFORE, Plaintiff claims damages in an amount in excess of $75,000.00 exclusive of interest and costs, and demands judgment in her favor and against all other parties.

COUNT III- SURVIVAL ACTION

Failure to Warn
Plaintiff Eva S. Sloan, Executrix of the Estate of Lois L. Eskind, Deceased v. Defendants

64. Plaintiff incorporates the preceding paragraphs 1 through 63 inclusive, as if fully set forth herein at length

65. The defendants and Dr. Sachs, acting as the defendants' co-conspirator in furtherance of the conspiracy, intentionally, willfully, wantonly, maliciously, and recklessly failed to warn the plaintiff's decedent of the following facts and failed to ensure that such warnings were provided to the plaintiff's decedent by another person:

(a) Surgery for treatment of vertebral compression fractures using Norian SRS or Norian XR involved the use of an illegally promoted medical device that was not approved by the FDA for that use, and that the FDA had explicitly warned should not be so used;

(b) Surgery for treatment of vertebral compression fractures using Norian SRS or Norian XR posed a unique serious and unreasonable risk of severe harm and death;

(c) Surgery for treatment of vertebral compression fractures using Norian SRS or Norian XR was experimental and was part an illegal clinical test of a medical device, and patients undergoing such surgery were being used as a human guinea pigs;

(d) Dr. Sachs had a financial interest in the use of Norian SRS and Norian XR in treating vertebral compression fractures and, therefore, had a conflict of interest in recommending surgery using Norian SRS and Norian XR;

(e) There were other less risky methods of treatment.

66. Because Dr. Sachs was a co-conspirator in the defendants' illegal conspiracy, one of the common purposes of which was to conceal from the public, including the plaintiff's decedents, the forgoing facts, he did not qualify as a "learned intermediary," and the defendants were legally required to provide full and adequate warnings directly to the plaintiff's decedent or to ensure that such warnings were provided to the plaintiff's decedent by another person.

67. The aforementioned failure by the defendants to provide full and adequate warnings and information directly to the plaintiff's decedent or to ensure that such warnings were provided to the plaintiff's decedent by another person was the direct, proximate, and producing cause of:

(a) the plaintiff's decedent's assenting to the aforementioned surgery, and the plaintiff's decedent's undergoing said surgery;

(b) the plaintiff's decedent's death during surgery;

(c) the injury and damages suffered by the plaintiff's decedent's husband and children as more fully set forth below.

WHEREFORE, Plaintiff claims damages in an amount in excess of $75,000.00 exclusive of interest and costs, and demands judgment in her favor and against all other parties.

COUNT IV – SURVIVAL ACTION

Gross Negligence
Plaintiff Eva S. Sloan, Executrix of the Estate of Lois L. Eskind, Deceased v. Defendants

68. Plaintiff incorporates the preceding paragraphs 1 through 67 inclusive, as if fully set forth herein at length

69. The foregoing acts and omissions of the defendants when viewed objectively from the standpoint of the defendants at the time of their occurrence involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others.

70. Therefore, the foregoing acts and omissions of the defendants constituted gross negligence.

71. The defendants' gross negligence was a direct, proximate, and producing cause of:

(a) impeding the FDA from performing its lawful functions to protect the health and safety of the public, including plaintiff's decedent, by ensuring that Norian SRS and Norian XR were safe and effective for their intended use, and from enforcing the FDC Act by preventing the illegal and unreasonably dangerous use of Norian SRS and Norian XR in surgery to treat vertebral compression fractures;

(b) the vigorous promotion by the defendants' sales force of Norian SRS and Norian XR to physicians for use in vertebroplasties and kyphoplasties in treating vertebral compression fractures;

(c) the failure of Dr. Sachs' to warn the plaintiff's decedent of the serious and unreasonable risks of the surgery she agreed to undergo on January 13, 2003, and Dr. Sachs' performing said surgery on plaintiff's decedent on January 13, 2003, without the patient's informed consent;

(d) the plaintiff's decedent's uninformed consent to the aforementioned surgery, and the plaintiff's decedent's undergoing said surgery;

(e) the plaintiff's decedent's death during surgery;

(f) the injury and damages suffered by the plaintiff's decedent's husband and children as more fully set forth below.

WHEREFORE, Plaintiff claims damages in an amount in excess of $75,000.00 exclusive of interest and costs, and demands judgment in her favor and against all other parties.

COUNT V – SURVIVAL ACTION

Negligence Per Se
Plaintiff Eva S. Sloan, Executrix of the Estate of Lois L. Eskind, Deceased v. Defendants

72. Plaintiff incorporates the preceding paragraphs 1 through 71 inclusive, as if fully set forth herein at length.

73. The foregoing acts and omissions of the defendants were in violation of the FDC Act and the regulations promulgated pursuant thereto as set forth above.

74. The plaintiff' decedent and the husband and children of the plaintiff's decedent were within the class of persons which the FDC Act and the regulations promulgated pursuant thereto were designed to protect.

75. Therefore, the foregoing acts and omissions of the defendants constituted negligence per se.

76. The defendants' negligence per se was the direct, proximate, and producing cause of:

(a) impeding the FDA from performing its lawful functions to protect the health and safety of the public, including plaintiff's decedent, by ensuring that Norian SRS and Norian XR were safe and effective for their intended use, and from enforcing the FDC Act by

preventing the illegal and unreasonably dangerous use of Norian SRS and Norian XR in surgery to treat vertebral compression fractures;

(b) the vigorous promotion by the defendants' sales force of Norian SRS and Norian XR to physicians for use in vertebroplasties and kyphoplasties in treating vertebral compression fractures;

(c) the failure of Dr. Sachs' to warn the plaintiff's decedent of the serious and unreasonable risks of the surgery she agreed to undergo on January 13, 2003, and Dr. Sachs' performing said surgery on plaintiff's decedent on January 13, 2003, without the patient's informed consent;

(d) the plaintiff's decedent's uninformed consent to the aforementioned surgery, and the plaintiff's decedent's undergoing said surgery;

(e) the plaintiff's decedent's death during surgery;

(f) the injury and damages suffered by the plaintiff's decedent's husband and children as more fully set forth below.

Wherefore, Plaintiff claims damages in an amount in excess of $75,000.00 exclusive of interest and costs, and demands judgment in her favor and against all other parties.

COUNT VI

SURVIVAL ACTION
Fraudulent Concealment
Plaintiff Eva S. Sloan, Executrix of the Estate of Lois L. Eskind, Deceased v. Defendants

77. Plaintiff incorporates the preceding paragraphs 1 through 76 inclusive, as if fully set forth herein at length

78. As set forth above, the defendants conduct was illegal in direct violation of the FDC Act and was tortious.

79. At all times relevant hereto, the defendants had actual subjective knowledge that their conduct was illegal and in direct violation of the FDC Act and was tortious and that their conduct was the direct, proximate, and producing cause of the death of the plaintiff's decedent.

80. As set forth above, the defendants and their co-conspirator, Dr. Sachs knowingly and intentionally used fraudulent deception and concealment for the purpose of concealing the defendants' illegal and tortious conduct, the wrong that was committed against the plaintiff's decedent and her husband and children, the facts that were the basis of their illegal and tortious conduct, and the fact that their said conduct caused the death of the plaintiff's decedent.

81. As set forth above, said fraudulent deception and concealment consisted of both affirmative, independent deceitful conduct on the part of the defendants and Dr. Sachs and the defendants' and Dr. Sachs' failure to disclose facts they were under a duty to disclose under the FDC Act, under the physician-patient relationship, and under the circumstances.

82. The plaintiff and plaintiff's decedent's husband and children reasonably relied on the defendants' and Dr. Sachs' fraudulent deception and concealment, which caused them to relax there vigilance and deviate from their right of inquiry into the facts, and in the exercise of reasonable care and diligence did not discover and should not have discovered the defendants' illegal or tortious conduct, the defendants' wrong, the defendants' fraudulently deceitful conduct, or the facts that were the basis of the defendants' illegal conduct, tort and wrong, including the cause of the death of the plaintiff's decedent, until the

illegal conduct, the tort, the wrong, the deceitful conduct, and the facts were called to their attention by a newspaper reporter in the summer of 2011.

83. Because of the aforementioned fraudulent concealment by the defendants and their co-conspirator, Dr. Sachs, the accrual of the instant causes of action was deferred, the statute of limitations was tolled, and the defendants are estopped under both the law of Texas and the law of Pennsylvania from raising the statute of limitations as a defense to the present action.

WHEREFORE, Plaintiff claims damages in an amount in excess of $75,000.00 exclusive of interest and costs, and demands judgment in her favor and against all other parties.

COUNT VII - NEGLIGENCE

Wrongful Death Action
Plaintiff Eva S. Sloan, Individually and as Executrix of the Estate of Lois L. Eskind, Deceased v. Defendants

84. Plaintiff incorporates the preceding paragraphs 1 through 83 inclusive, as if fully set forth herein at length

85. At the time of her death, Lois L. Eskind was survived by her husband, Isaac Joseph Eskind, Jr., her daughter Eva S. Sloan, and her son Roger Lee McConnell, a/k/a Capt Mac.

86. Plaintiff, Eva S. Sloan, as Executrix of the Estate of Lois L. Eskind, brings this wrongful death action on behalf of Isaac Joseph Eskind, Roger Lee McConnell, and herself.

87. None of the individuals entitled to bring an action for the wrongful death of plaintiff's decedent have begun such action within three calendar months after the death of

the plaintiff's decedent, and none of said individuals have requested the plaintiff not to bring this action.

88. As a direct, proximate and producing result of the death of the plaintiff's decedent, her surviving spouse, Isaac Joseph Eskind, Jr., and her surviving children, Eva S. Sloan and Roger Lee McConnell have each suffered a high degree of mental anguish, including include painful emotions, grief, severe disappointment, indignation, and despair.

89. As a further direct and proximate result of the death of the plaintiff's decedent, her surviving spouse, Isaac Joseph Eskind, Jr., and her surviving children, Eva S. Sloan and Roger Lee McConnell have each suffered pecuniary loss, including but not limited to the loss of the decedent's companionship, society, support, assistance, service, comfort and affection.

90. By reason of the death of Lois L. Eskind, her estate has incurred expenses, including but not limited to, funeral and burial expenses and costs of administration of the estate.

91. Plaintiff, Eva S. Sloan, brings this action by virtue of, and seeks all damages recoverable under the Wrongful Death Act, 42 Pa. C.S. § 8301, et seq. and Pa. R. C. P. 2202 (a).

92. Because the death of the plaintiff's decedent and the resulting damages to the surviving spouse of the decedent and the decedent's children were directly and proximately caused by the defendants' intentional, willful, wanton, malicious, and reckless misconduct, gross negligence, fraud, and conspiracy, the plaintiff claims punitive or exemplary damages as well as compensatory damages.

WHEREFORE, the plaintiff claims damages in an amount in excess of $75,000, exclusive of interest and costs, and judgment in her favor and against all other parties.

FELDMAN & PINTO

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